

UNITED STATES DISTRICT COURT  
DISTRICT OF MAINE

DIANE RONEY, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil No. 2:05-cv-109-GZS
	)	
WENDY'S OLD FASHIONED	)	
HAMBURGERS OF NEW YORK, INC.,	)	
	)	
Defendant.	)	

**AMENDED<sup>1</sup>**  
**MEMORANDUM OF DECISION ON DEFENDANT'S MOTION TO BAR EXPERT**  
**TESTIMONY AND PLAINTIFF'S MOTION TO STRIKE AND**  
**RECOMMENDED DECISION ON DEFENDANT'S**  
**MOTION FOR SUMMARY JUDGMENT**

Wendy's Old Fashioned Hamburgers of New York, Inc., has moved to bar Diane Roney's causation expert, Dr. Owen Pickus, from offering an opinion that Roney's experience of renal failure (kidney failure) and severe thrombocytopenia (diminished platelet count) in March 2001 was proximately caused by her ingestion of an undercooked hamburger at Wendy's Saco restaurant. Wendy's also moves for summary judgment. Also before the court is a motion to strike that arises from the parties' Local Rule 56 statements. I deny the Motion to Bar Expert Testimony, deny the Motion to Strike and recommend that the Court deny the Motion for Summary Judgment.

**Background Facts**

The following statement of facts is drawn from the parties' Local Rule 56 statements of material fact in accordance with this District's summary judgment practice. See Doe v. Solvay Pharms., Inc., 350 F. Supp. 2d 257, 259-60 (D. Me. 2004) (outlining the procedure); Toomey v.

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<sup>1</sup> The only amendment is typographical, on page two, fifth line from bottom, the word "foul" is corrected to "fowl".

Unum Life Ins. Co., 324 F. Supp. 2d 220, 221 n.1 (D. Me. 2004) (explaining the "the spirit and purpose" of Local Rule 56). Pursuant to Rule 56 of the Federal Rules of Civil Procedure, all evidentiary disputes appropriately generated by the parties' statements have been resolved, for purposes of summary judgment only, in favor of the non-movant. Merchants Ins. Co. v. United States Fid. & Guar. Co., 143 F.3d 5, 7 (1st Cir. 1998).

Wendy's Old Fashioned Hamburgers of New York, Inc., operates the Wendy's Restaurant in Saco, Maine. (Def.'s Statement of Material Facts (SMF) ¶ 1, Docket No. 36.) Every stage of Wendy's hamburger production service, from the initial butchering of cows to the cooking and serving of individually packaged hamburgers involves safety procedures and testing to ward against the known risk of bacterial contamination, including contamination by E. coli 0157:H7, generic E. coli, Salmonella and Listeria. (Id. ¶¶ 2-28.) In addition to this oversight, Wendy's maintains a database of all personal injury claims made against Wendy's, including "foodborne illness claims." (Id. ¶¶ 29-33.) Other than the incident described herein, Wendy's received no other complaints "arising from the sale and/or consumption of any food product sold by the Saco, Maine location in the year 2001." (Id. ¶ 35.)

Diane Roney resides in Standish, Maine, with her husband and two sons. (Id. ¶¶ 92, 98; Pl.'s Add'l Statement of Material Facts (Add'l SMF) ¶ 2, Docket No. 39, Elec. Attach. 1.) Diane Roney prepares all meals for her family and they consume, among other things, eggs, milk, beef, pork, fowl and fish. (SMF ¶ 95.) The Roney family would not go an entire week without eating any type of beef product, lamb product, or pork product. (Id. ¶ 110.) Roney's husband, Paul, was a facilities director for the Gorham School Department and regularly visited elementary schools during the time relevant to this lawsuit. (Id. ¶ 97.) Roney also worked in the school environment as an educational technician in elementary level classrooms. (Id. ¶ 101; Add'l SMF

¶ 3.) Roney does not recall her food intake, or where she ventured other than her place of employment and home, between February 23, 2001 and February 28, 2001. (SMF ¶ 108.)

On March 1, 2001, a Thursday, Roney went to work at Edna Libby Elementary School, and then went to Howard's Sports Center in Saco to watch her sons play lacrosse. (Id. ¶ 107; Add'l SMF ¶ 5.) It is possible that she used the restroom facilities at the sports center. (SMF ¶ 107.) That evening at approximately 6:30 p.m., Roney, her husband Paul and her two sons went to eat at the Wendy's in Saco, Maine. (Id. ¶ 111.) Paul Roney went into the bathroom, where he observed a Wendy's employee come out of the toilet stall and rinse his hands under running water, without using soap. (Add'l SMF ¶¶ 6-7.) Meanwhile, Diane Roney placed the order for her family, consisting of four bacon cheeseburgers. (SMF ¶ 112.) Three bacon cheeseburgers were placed on her tray, and fifteen seconds later the fourth cheeseburger arrived. (Id. ¶ 113.) The Roneys dined in and Roney took two bites from her cheeseburger before cutting it in half because it was messy. (Id. ¶ 115.) According to Roney, roughly a tablespoon of blood came out of the sandwich when she did so and she observed that the bun was saturated with blood. (Id.; Add'l SMF ¶ 16.) She describes the blood as being akin to the blood that would come out of a fresh wound. (SMF ¶ 116.) Roney lost her appetite and did not finish the cheeseburger. She did not complain to the staff of the restaurant. (Id. ¶ 117.) Instead, she simply discarded the remains of the cheeseburger in the trash. (Id. ¶ 121.) Paul Roney and the Roney boys finished their cheeseburgers, none of which leaked any blood. (Id. ¶ 118.) Of the four of them, only Diane Roney became ill over the next few days. (Id. ¶ 119.)

Roney began feeling ill—stomach pains and pain radiating into her back—beginning on Friday, March 2. (Add'l SMF ¶ 23.) She attended work and went to another lacrosse game that afternoon. (SMF ¶ 127.) She was still experiencing abdominal pain radiating into her back.

(Id.) That evening she experienced diarrhea and frequent urination. (Id. ¶ 128.) Roney did not observe whether her diarrhea was bloody. (Id.) In the afternoon of the following day, Saturday, March 3, 2001, Roney called an ambulance because her abdominal pain had become excruciating and her urine had turned brown. (Id. ¶¶ 129, 131; Add'l SMF ¶¶ 29-32.)

Most patients (80-90%) who suffer infection from E. coli strain 0157:H7 present for treatment with symptoms including hemorrhagic (bloody) diarrhea, which means, of course, that as many as 20% do not. (SMF ¶ 268.) Roney did not inspect the contents of the toilet bowl to determine whether there was blood present. (Add'l SMF ¶ 28.) Although Roney would like to generate a genuine issue as to whether bloody diarrhea was among the symptoms she experienced prior to admission on March 3, 2001, I conclude that the summary judgment record cannot support such a finding because even Roney fails to state that she has a legitimate basis in personal knowledge to draw that conclusion. (Id.) In any event, all of the experts and treating physicians, including Dr. Pickus, have proceeded on the understanding that Roney did not experience symptoms of bloody diarrhea.

The ambulance transported Roney to Mercy Hospital. Following her admission to Mercy Hospital, Roney was no longer experiencing diarrhea or urinating. She surmises that she was "out of liquid" by that point. (Add'l SMF ¶ 40.) Mercy transferred Roney to Maine Medical for purposes of receiving plasmapheresis. (SMF ¶ 164.) Several days after her hospital admission, on March 11, 2001, a stool culture was taken and lab results indicated that E. coli 0157:H7 was not present in the culture. (Id. ¶ 173.) According to Roney's trial expert, Dr. Owen Pickus, DO, FACOI, that culture has no tendency to establish whether E. coli was present in Roney when she presented for care because the culture was taken more than a week after treatment had ensued.<sup>2</sup> (Id. ¶ 277; Opposing Statement of Material Facts (Opp. SMF) ¶ 173; Add'l SMF ¶ 99.) Dr.

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<sup>2</sup> This fact is disputed. (Def.'s Reply Statement of Material Facts ¶ 99.)

Pickus believes that Roney's treating physicians simply neglected to take a culture in a timely fashion. (Add'l SMF ¶¶ 100-101.) It is elsewhere agreed that Roney's "counts" were back to normal and she was feeling well as of May 8, 2001. (SMF ¶ 189; see also id. ¶ 195.)

Dr. Pickus would opine at trial that, more likely than not, Roney suffered acute renal failure and severe thrombocytopenia in March 2001 because the undercooked hamburger she partially consumed on March 1, 2001, was contaminated with E. coli bacteria. (Add'l SMF ¶ 63.) Dr. Pickus is board certified in internal medicine with a subspecialty and board certification in oncology and hematology. (Id. ¶ 237.) His opinion is based on a review of Roney's medical records, his treatment of Ms. Roney, and his education, training and experience. (Add'l SMF ¶ 60.) He has also reviewed the affidavits of Wendy's experts and the transcripts of the depositions taken from Roney's treating physicians at Mercy Hospital and Maine Medical. (Id.) In Dr. Pickus's view, the most likely cause of Roney's illness was E. coli induced HUS (hemolytic uremic syndrome) originating from the uncooked Wendy's cheeseburger, but he allowed during his deposition that she "could have had a lot of things." (SMF ¶ 348, citing Pickus Dep. at 121.) Still, he personally believes it unlikely that it was something other than HUS mediated by E. coli infection because, in his view, there is no more persuasive circumstantial evidence of any other cause and the alternatives suggested by Wendy's experts are less consistent with the available data, making E. coli infection "what most likely makes sense." (Id. ¶ 332, citing Pickus Dep. at 148). As for the cheeseburger being a potential source of E. coli, Wendy's itself places in the summary judgment record the fact that "[t]he most common source of HUS cases in this country are from undercooked hamburger" and it admits Roney's statement that "80 to 90 [percent] or more of the HUS cases in this country are from undercooked hamburger." (SMF ¶ 270; Add'l SMF ¶ 80.) According to Dr. Pickus, the hamburger likely was the source of the alleged E. coli

infection because it was uncooked and, thus, in a condition known to present a significant risk.

(Add'l SMF ¶ 85: "Given those circumstances, you would have to lean in the direction of concluding that the rare hamburger caused an E. coli 0157 infection.") On the other hand, Dr. Pickus is willing to concede that it would not be unreasonable for other medical experts to disagree with his diagnosis. Thus:

Dr. Pickus believes it was reasonable for plaintiff's treating hematologist, Dr. Jacquelyn Hedlund, M.D, to conclude that, without diarrhea, it is unlikely plaintiff had an E. coli 0157:H7 infection because only 15 percent of E. coli 0157:H7 cases present without bloody diarrhea; Dr. Pickus believes plaintiff was among that 15 percent.

(SMF ¶ 324.)

Dr. Pickus concedes that other diagnoses could be considered for both the July 2000 and March 2001 admissions and other doctors could reach different conclusions based on the same evidence.

(Id. ¶ 335.)

Wendy's experts disagree with this conclusion and maintain that other, equally plausible explanations have not been ruled out by Dr. Pickus, rendering his opinion unreliable. One of these three experts, Dr. Anthony Mega, believes that Roney experienced a case of recurrent TTP, a conclusion that Wendy's says Dr. Pickus is unqualified to challenge. The basis for this alternative diagnosis is that once before, in the summer of 2000, Roney presented herself at a hospital with symptoms of severe gastric distress. At that time Roney had abdominal pain, a low platelet count and a high bilirubin measurement, which can be indicative of red blood cell destruction. (Id. ¶ 59.) Dr. Mega opines that Roney had a case of TTP in 2000 and a recurrence of that condition in 2001. (Id. ¶¶ 59-65.) TTP is an acquired deficiency in the enzyme ADAMTS 13, which deficiency prevents a person from cleaning a protein from the blood, whereas HUS due to E. coli toxin is a direct injury to the membranes of blood cells that "leads to

the same process as TTP" (which I infer to mean the same or similar problems in kidney function). (*Id.* ¶¶ 62-63.) Although enzyme deficiency causes TTP, not all of the causes of the enzyme deficiency are known. (*Id.* ¶ 321.) It appears that a test has been devised to determine whether a person has the enzyme deficiency associated with TTP, but no one has conducted such a test on Roney to this date. (SMF ¶ 304.) There is no indication in the record that the test is reliable, readily available or even reasonably affordable.

### **Discussion**

Wendy's contends that the medical opinion of Roney's causation expert, Dr. Pickus, is inadmissible under Rule 702 of the Rules of Evidence and is otherwise insufficient to support a finding that the cheeseburger Roney partially ingested was the proximate cause of her illness.

#### **A. Motion to Bar Testimony**

Pursuant to Rule 702 of the Federal Rules of Evidence:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

In Daubert v. Merrell Dow Pharms, Inc., 509 U.S. 579 (1993), the Supreme Court discussed the gate-keeping role federal judges play under Rule 702 in screening from introduction in evidence expert testimony that, although relevant, is nevertheless based on unreliable scientific methodologies. *Id.* at 597. That role is "to ensure that an expert's testimony 'both rests on a reliable foundation and is relevant to the task at hand.'" United States v. Mooney, 315 F.3d 54, 62 (1st Cir. 2002). In General Elec. Co. v. Joiner, 522 U.S. 136 (1997), the Supreme Court explained that a judge exercising this duty must evaluate whether the challenged expert

testimony is based on reliable scientific principles and methodologies in order to ensure that expert opinions are not "connected to existing data only by the ipse dixit of the expert." Id. at

146. To aid in this task, the Court assigned the following non-exclusive, four-factor standard:

(1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; and (4) the level of the theory or technique's acceptance within the relevant discipline.

Mooney, 315 F.3d at 62 (citing Daubert, 509 U.S. at 593-94). The technique discussed herein, differential diagnosis, generally satisfies this test, assuming it is adequately performed. Baker v. Dalkon Shield Claimants Trust, 156 F.3d 248, 252 (1st Cir. 1998). In addition to these factors, the trial court may consider other factors that are probative of reliability in light of the particular facts and circumstances of the case at hand. Id. Ultimately, the proponent of the expert testimony must simply establish that it is reliable. The proponent is not required to prove that the expert's opinion is correct. Id. at 63. "Once a trial judge determines the reliability of the expert's methodology and the validity of his reasoning, the expert should be permitted to testify as to inferences and conclusions he draws from it and any flaws in his opinion may be exposed through cross-examination or competing expert testimony." Brown v. Wal-Mart Stores, Inc., 402 F. Supp. 2d 303, 308 (D. Me. 2005). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596.

Wendy's motion to bar Dr. Pickus's testimony asks that the Court bar Dr. Pickus "from offering any opinion that plaintiff did not have relapsing TTP or that plaintiff's illness resulted from an E. coli 0157:H7 infection caused by a Wendy's hamburger." (Mot. to Bar Expert Testimony at 1, Docket No. 35.) I take these challenges in turn, but note at the outset that the case for proving causation is complicated by two facts: (1) the subject bacon cheeseburger was



discarded and, hence, could not be examined for the presence of E. coli bacteria and (2) a timely stool culture or other culture was not taken from Roney to screen for the presence of E. coli upon her presentation for medical care. Nevertheless, the absence of a culture does not automatically preclude a physician from finding that a certain etiology (cause or origin of disease) is more likely than any other. See, e.g., Winnicki v. Bennigan's, Civ. No. 01-3357, 2006 U.S. Dist. LEXIS 5568 (D. N.J. Feb. 9, 2006) (unpub. op. on mot. to bar expert test.) (denying a motion to bar expert testimony that food poisoning from a Caesar salad was the cause of renal failure in a teenage girl despite the absence of any timely cultures and where defendant's expert opined that E. coli-induced HUS could not be diagnosed because the plaintiff had not developed "a classical case of diarrhea associated HUS"). In fact, if a culture were required, there would be little point in performing a differential diagnosis in the first place, yet clearly all of the experts in this case have evaluated causation using the differential approach. Thus, although Dr. Pickus conceded during his deposition that, because there were no cultures, "we're left with inferences," and, although "inferences can be useful, . . . they're not as good as a culture," (SMF ¶ 289; Pickus Dep. at 104), I am not persuaded that the absence of a culture precludes Dr. Pickus from offering a "more likely than not" causation opinion that points to E. coli 0157:H7 mediated HUS and the Wendy's cheeseburger.

***1. Dr. Pickus's exclusion of recurrent TTP***

Anthony Mega, M.D., Wendy's hematology and oncology expert, opines that Roney suffered from TTP (thrombotic thrombocytopenic purpura) in both 2000 and 2001 because TTP is known to recur and responds well to plasma exchange. (Mega Aff. ¶ 4(j).) Dr. Mega asserts that TTP and HUS are closely related but he chooses TTP as the most likely culprit. In his view, Roney's symptoms were inconsistent with classic or typical HUS because her symptoms came on

too soon after the ingestion of the burger and did not include bloody diarrhea and also because there was no epidemiologic cluster in the area served by the subject Wendy's restaurant. (Id. ¶ 4.) Wendy's argues that Dr. Pickus should not be heard to contest this diagnosis because Dr. Pickus lacks first hand clinical experience with the recurrent TTP entity.

I agree with Roney that Dr. Pickus's lack of clinical experience with relapsing or recurrent TTP does not preclude him from opining that such a condition is less likely to have been the cause of Roney's renal complications in 2001. Dr. Pickus asserts that he is familiar with the disease by virtue of his education and medical research and has set forth his reasons for excluding that etiology: the absence of renal failure in connection with Roney's 2000 hospital visit, the return of platelet levels to normal upon removal of her Macrobid medication from her system,<sup>3</sup> the absence of neurological manifestations,<sup>4</sup> the absence of any symptoms consistent with chronic TTP in the five year period between her 2001 hospitalization and the present, and the fact that recurrent TTP is an extremely rare condition.

Wendy's asserts that Dr. Pickus confessed ignorance of the recurrent TTP condition during his deposition. That deposition testimony seems to reflect more that Dr. Pickus was not fully rehearsed during his deposition on recurrent TTP, which might suggest that he had not fully considered it at that time as part of his differential analysis. However, it is apparent from his affidavit that Dr. Pickus has since addressed such a possible etiology and excluded it based on the fact that Roney's platelet levels returned to normal in 2000 upon discontinuance of her Macrobid medication (which is inconsistent with Dr. Mega's enzyme deficiency theory) and that there is no evidence of any recurrence or chronic condition in all the years since Roney's 2001 hospitalization. In my view, these expert observations reflect that Wendy's alternative TTP

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<sup>3</sup> Dr. Pickus asserts that TTP would not have responded to a single administration of platelets. (Add'l SMF ¶¶ 88-91.)

<sup>4</sup> Note that "mental status changes" occur in only 30-50 percent of patients with TTP. (SMF ¶ 309.)

theory does not demonstrate the inadmissibility of Dr. Pickus's *E. coli* induced HUS theory, but only raise questions pertaining to the relative weight of the competing opinions. I also note that Dr. Mega's TTP diagnosis is not altogether unhelpful to Roney because Dr. Pickus's exclusion of TTP appears to advance the case for HUS and advances his differential diagnosis.<sup>5</sup> Dr. Pickus may be wrong, but his methodology appears to be reliable.<sup>6</sup>

## **2. Dr. Pickus's exclusion of alternative sources of *E. coli* infection**

Wendy's argues that Dr. Pickus's methodology is flawed because, even assuming contaminated food was the source of Roney's illness, Dr. Pickus does not know all of what Roney consumed in the days leading up to her 2001 hospitalization and also because he did not go to her place of employment to search for a potential alternative source of *E. coli* bacteria.

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<sup>5</sup> Wendy's acknowledges in its motion for summary judgment that the symptoms suggest "TTP and/or HUS." (Mot. Summ. J. at 6, Docket No. 34; see also SMF ¶ 194 (stating that Roney's medical records "indicate the interrelated disorders of TTP/HUS"). Roney's treating hematologist at Maine Medical Center considered the undifferentiated diagnosis of "TTP/HUS" to be the "most unifying diagnosis" as well. (SMF ¶ 194.)

<sup>6</sup> The relevant portions of Dr. Pickus's affidavit are as follows:

15. Speaking to Dr. Mega's conclusion that in 2001 Mrs. Roney suffered a bout of relapsed TTP, although I considered this diagnosis in the differential diagnosis, I believe that such a postulation is extremely remote. Of significance to me in ruling out TTP in her 2000 admission as a likely diagnosis, is that she did not suffer renal failure, as compared to her 2001 admission, and that her platelets rapidly returned to normal upon removal from her antibiotic medication.

16. Moving to Dr. D'Agata's belief that the 2001 hospital admission comprised relapsed TTP, I do not agree. As I explained earlier, I believe that the 2000 admission was caused by medication induced thrombocytopenia, which condition resolved itself once the medication was removed. Additionally, in her 2001 admission, she did not experience mental status changes, fever or schistocytes, which mitigates more toward primary HUS than TTP. Additionally, Mrs. Roney's 2001 admission was not accompanied by neurological manifestations, making the diagnosis of primary TTP far less likely. Furthermore, since the 2001 admission, Mrs. Roney has not exhibited any evidence of TTP, providing further support for my opinion that she does not have and did not have in 2000 or 2001, relapsing TTP.

17. Defendant claims that I lack the expertise to opine regarding chronic, relapsing TTP. This is not true. Chronic, relapsing TTP is a very rare diagnosis which few hematologists ever make, much like West Nile virus. Nonetheless, as a board certified hematologist, I am familiar with the illness. I am sufficiently familiar with the condition to address possible symptoms, and to consider and rule the diagnosis out in this case, which I have done. I did testify that I could not say "whether people with chronic, recurrent TTP have a low or subnormal platelet count." I was not saying, however, that I was unfamiliar with chronic, recurrent TTP. I was merely stating that with such a condition, it is not clear whether the patient's platelet count is persistently low all the time, even between outbreaks, or whether it simply vacillates between low and normal, over and over again. That is the piece of information that [I] am not familiar with – whether a patient with chronic, recurrent TTP would have a chronically low platelet count, even between outbreaks.

These facts, in my view, go to weight rather than admissibility. As Dr. Pickus observes, Roney and her family assert that she partially consumed an undercooked or uncooked hamburger roughly 40-48 hours prior to calling an ambulance to take her to the hospital. Insufficiently cooked ground beef presents a well-known hazard for E. coli infection. Although Roney ate other food within the relevant timeframe, including meat prepared in her home, it is significant that no one else in her family experienced similar infection. As for the potential for exposure at Roney's place of work, it is again significant that Roney should be the only individual known to have experienced such serious renal complications. However, the circumstances pertaining to her consumption of an uncooked hamburger patty, which Dr. Pickus was permitted to credit, are consistent with individual infection. The absence of an epidemiologic cluster, which appears to be something all of the experts rely on, is consistent with individual infection due to individual consumption of uncooked ground beef.

Another of Wendy's experts, Dr. Bradley Denker, M.D., board certified in internal medicine with a subspecialty in nephrology, opines that Roney possibly suffered from "acute tubular necrosis" (ATN). (Denker Aff. ¶ 4(f).) Somewhat like Dr. Mega, Dr. Denker also opines that Roney had a "pre-existing condition" from 2000 and that her 2000 and 2001 illnesses were "identical." (Id. ¶ 4(a).) Dr. Pickus rejects the characterization of the 2000 and 2001 episodes as identical or even related. According to him Roney's 2000 symptoms were caused entirely by a medication she was taking at the time. He draws this conclusion because the medication she was taking at that time is well-known to cause that condition and the symptoms disappeared promptly upon removal of the medication from her system. (Pickus Aff. ¶¶ 4-5.) As for Dr. Denker's suggestion that Roney's was a case of ATN, Dr. Pickus observes that he excluded this possibility

because Roney had low platelets and responded to plasmapheresis, which, according to him, is inconsistent with an ATN diagnosis. (Pickus Aff. ¶ 14.)

### 3. *Dr. Pickus's inclusion of E. coli*

Erika D'Agata, M.D., one of Wendy's medical experts who is board certified in infectious disease medicine, opines that the Wendy's burger could not have been the source of *E. coli* because of "the lack of *conclusive* evidence supporting the diagnosis." (D'Agata Aff. ¶ 4(a) (emphasis added), Docket No. 36, Elec. Attach. 5.) This opinion is premised, largely, on the absence of a positive indication of bloody diarrhea at or following Roney's hospital admission. (*Id.*) Furthermore, D'Agata notes that *E. coli* normally has a longer incubation period than 24 to 48 hours and that bloody diarrhea (when there is any) normally commences at approximately 72 hours.<sup>7</sup> (*Id.* ¶¶ 4(a), (b).) As for the HUS diagnosis, D'Agata observes that no blood smears were acquired to determine the existence of schistocytes (damaged red blood cells). (*Id.* ¶ 4(d).) Dr. D'Agata does not offer an alternative diagnosis. Dr. Denker also opines that Roney did not have "HUS/TTP" in March 2001 based on the absence of bloody diarrhea and the timing of any diarrhea symptoms, and also based on the "absence of any microangiopathic changes or schistocytes on multiple smears." (Denker Aff. ¶ 4(b), (h), Docket No. 36, Elec. Attach. 7.) Like Dr. D'Agata, Dr. Denker also rules out *E. coli* "based on the lack of *conclusive* evidence supporting the diagnosis." (*Id.* ¶ 4(h) (emphasis added).) Part of Dr. Denker's opinion is in tension with Dr. Mega's opinion that TTP was the entity that made Roney ill. Dr. Mega otherwise joins in the chorus that Roney's symptoms were inconsistent with the typical case of *E.*

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<sup>7</sup> I find the timing evidence to be inconclusive. Wendy's experts all point to the timing and non-existence of bloody diarrhea as significant evidence, but Roney presented herself at the hospital before 72 hours had elapsed. Thus, the absence of bloody diarrhea prior to admission does not seem highly probative to me. None of the experts suggest that gastric pain could not have commenced along the timeline described by Roney. Also, it appears to be uncontested that bloody diarrhea is not present in roughly 15 percent of known cases of *E. coli* infection. Dr. Pickus asserts that *E. coli* induced HUS would likely lead to renal shutdown within 72 to 96 hours from ingestion, but renal impairment within two to three days. (SMF ¶ 349.)

coli infection based primarily on the timing of the symptoms, the absence of bloody diarrhea and the absence of an epidemiologic outbreak in the area of the subject restaurant. (Mega Aff. ¶ 4.)

Dr. Pickus's affidavit asserts that the absence of schistocytes from smears taken in 2001 is more consistent with HUS than it is with TTP. (Pickus Aff. ¶ 16.) Dr. Denker's affidavit could be read to agree with the statement that the absence of schistocytes is inconsistent with TTP. In it, he asserts that the "absence of schistocytes or fragmented red blood cells supports [the] conclusion that plaintiff did not have TTP in [ ] March of 2001." (Denker Aff. ¶ 4(c).) Dr. Pickus does not contest the assertion that Roney's illness was inconsistent with a classic or typical case of E. coli infection because of the absence of bloody diarrhea, but notes that it is medically recognized that roughly 15 percent of individuals with E. coli infection present without diarrhea symptoms. Dr. Pickus asserts that the causal link between E. coli 0157 infections and HUS is well-documented in the medical literature. (Pickus Aff. ¶ 7.) His reasoning for opining that E. coli 0157 caused HUS in Roney is as follows:

8. The basis for my opinion that Mrs. Roney's illness in March 2001 began with an E. coli 0157 infection from an undercooked hamburger from Wendy's is that Mrs. Roney reports eating part of a hamburger that was undercooked or uncooked. When cut open, this hamburger oozed what looked to Mrs. Roney like a tablespoon or more of "wound" type, red blood. In addition, the hamburger looked raw to Mrs. Roney, and to others who witnessed the event. Assuming Mrs. Roney's account to be accurate, she ingested an undercooked/raw hamburger on March 1, 2001. The medical literature is replete with reports and studies indicating that the most common mode of transmission of E. coli 0157 in the United States is, in fact, undercooked meat, particularly hamburgers. Indeed, the medical literature as well as popular magazines and newspapers have for years suggested or encouraged any one or entity preparing hamburgers to be sure they are fully cooked in order to destroy any E. coli 0157 bacteria contamination which unfortunately, is well known to be one of the risks and by-products of butchering (at least non-kosher butchering) .

9. Defendant raises the possibility that Mrs. Roney might have contracted the E. coli 0157 bacteria through some other mode of transmission, most notably from some other food source or from contamination from the students she was working with at the time who might not have cleaned themselves properly after

using the washroom. The medical literature is clear and prolific in stating that undercooked meat is, far and away, the most common cause of E. coli 0157 infections. I am not aware that there is any epidemiological evidence of any other source of E. coli 0157 contamination or infection in Mrs. Roney's geographical area on or around March 2001. No outbreaks of E. coli 0157 were reported as far as I am aware. If other food sources were contaminated with E. coli 0157 in Mrs. Roney's geographic area at that same time, it is likely an outbreak would have been reported. If E. coli 0157 were present in Mrs. Roney's workplace, again, it is likely that an outbreak would have been reported. In any event, these other proposed modes of transmission are much less likely than an undercooked hamburger, and there is simply no evidence of any kind to support these alternate source theories.

10. Additionally, Defendant argues that I did not "rule out" all of the items of food that Mrs. Roney consumed in the days before she ate the undercooked/raw hamburger and so I have failed to work up a medically sound differential diagnosis. Clearly, it would have been impossible to analyze food that had already been ingested or discarded. Again, however, I am unaware of any evidence of any E. coli 0157 outbreak in the State of Maine on or around March 2001, regardless of source. The hamburger that Mrs. Roney bit into was in a defective and unsafe condition, known in the medical literature to be the most significant causative agent for E. coli 0157 infection; conversely, there is no evidence of which I am aware that any of the other foodstuffs consumed by Mrs. Roney appeared, smelled, or tasted out of the ordinary. This of course contrasts markedly with the condition of the Wendy's hamburger that she ingested on March 1, 2001, which looked, felt, and tasted undercooked or raw, which is a well-known, dangerous condition.

11. I am aware that there is no evidence of any outbreak of E. coli 0157 infection stemming from hamburgers prepared by the Wendy's restaurant where Mrs. Roney bought her hamburger on March 1, 2001. I am heartened to learn this, but that fortuity (had other hamburgers emerged from the kitchen at Wendy's in an undercooked or raw condition there might indeed have been an outbreak of E. coli 0157 infection) does not change the fact that on March 1, 2001 the hamburger prepared and sold to Mrs. Roney was bloody and undercooked, which is a defective condition that, unfortunately, is well-known to present a significant risk of E. coli 0157 infection.

The foregoing analysis clearly "rules in" E. coli as a potential cause, though it is not conclusive by any means. In my view, this assessment, when coupled with the exclusion of the various alternative causes raised by Wendy's experts, demonstrates that Dr. Pickus's expert opinion—such as it is—is premised upon a reliable methodology (differential diagnosis) and is therefore

admissible in evidence regardless of whether it constitutes conclusive proof of a causal connection between Wendy's service of an uncooked cheeseburger and Roney's development of renal complications over the next several days. I therefore deny the Motion to Bar Expert Testimony.

**B. Motion to Strike**

Roney has moved to strike Wendy's Reply Statement of Material Facts and the supporting affidavit of Jennifer Stefanek, food safety director of Smithfield Beef Group, which owns the Moyer Packing Company in Souderton, Pennsylvania. (Mot. to Strike, Docket No. 46.) Roney complains that Wendy's improperly replied to many of her opposing statements of material facts and not just to her additional statements of material facts. I have had no occasion to either present or modify any of the facts recited herein on account of Wendy's reply concerning its original 361 statements of fact. I further observe that neither my ruling on the Motion to Bar Expert Testimony nor my recommended decision on the Summary Judgment Motion turns in any way on that portion of the record that is supported by the testimony offered by Ms. Stefanek. The particulars of the safety measures employed by Wendy's and its providers are, of course, relevant to this litigation, but in the context of the pending summary judgment motion, which challenges the existence of proximate causation rather than breach of duty, the safety procedures followed by Wendy's and its providers serve primarily as evidence that Wendy's is on notice of the serious health risk posed by the potential for ground beef to become tainted by E. coli 0157:H7. In any event, it would be inappropriate in the context of a summary judgment motion to infer from this evidence that the subject cheeseburger could not possibly have been contaminated with E. coli 0157:H7. For the foregoing reasons, I consider the Motion to Strike to be much ado about nothing and deny it as moot.



### C. Motion for Summary Judgment

Wendy's summary judgment motion is premised entirely on the argument that Roney fails to generate a genuine issue of material fact that the Wendy's cheeseburger proximately caused her illness. (Mot. Summ. J. at 2.) As Wendy's notes, proximate cause is an element of each of the Roneys' claims. (Id. at 13-14.) "[P]roximate cause is that cause which, in natural and continuous sequence, unbroken by an efficient intervening cause, produces the injury, and without which the result would not have occurred." Merriam v. Wanger, 2000 ME 159, ¶ 8, 757 A.2d 778, 780 (quoting Searles v. Tr. of St. Joseph's Coll., 1997 ME 128, ¶ 8, 695 A.2d 1206, 1209). It is Roney's burden to prove that the Wendy's cheeseburger "more likely than not" was the proximate cause of her illness. Ricci v. Alternative Energy, Inc., 211 F.3d 157, 162 (1st Cir. 2000). As the "more likely than not" standard would suggest, "[t]he mere possibility of such causation is not enough, and when the matter remains one of pure speculation or conjecture, or even if the probabilities are evenly balanced, a defendant is entitled to a judgment." Id. at 781.

Ordinarily, the existence of proximate causation is a question of fact. Houde v. Millett, 2001 ME 183 ¶ 11, 787 A.2d 757, 759. "Nevertheless, if the evidence produced by the plaintiff in opposition to a motion for summary judgment would, if produced at trial, entitle the defendant to a judgment as a matter of law, the defendant is entitled to a summary judgment." Id. Thus, I ask myself whether any reasonable juror could conclude that Roney more likely than not contracted E. coli 0157:H7 induced HUS from the cheeseburger she ate on March 1, 2001, without feeling that their conclusion was based on "pure speculation or conjecture." I find this question to be an extremely close one to call. I conclude that such a juror could reasonably believe that the cheeseburger more likely than not was the cause of Roney's March 2001 renal failure and that her injuries were mediated by E. coli 0157 contamination. To begin, despite

Roney's prior visit to the hospital in 2000 for renal complications, I treat Roney as I would treat a theoretical plaintiff having no such prior history. Based on Dr. Pickus's expert testimony, a reasonable juror could conclude that Roney's 2000 visit was precipitated by her ingestion of Macrobid, and was not due to any preexisting or chronic enzyme deficiency. From there I ask whether a reasonable juror could also conclude that an individual with no prior or subsequent history of TTP and no prior or subsequent history of E. coli 0157:H7 infection from home meals or workplace exposure, who presented for treatment with symptoms consistent with roughly 15 percent of the known cases of E. coli 0157:H7 induced HUS, and who reported ingestion of uncooked ground beef within the past 48 hours—known to be involved in 80 to 90 percent of such cases—and who is experiencing severe gastric distress and is on a trajectory toward complete renal failure (likely to lead to death without medical intervention), more likely than not became infected with E. coli 0157:H7 from ingesting that uncooked ground beef. Based on my review of all the evidence, including the differential analysis played out in the parties' competing presentations on the Motion to Bar Expert Testimony, I think that such a finding would not be outside the bounds of reasonableness. That is not to say that I would not expect such a juror to have doubts about such a finding or to wish that the evidence were more persuasive. Clearly, it would be unreasonable for a juror to make such a finding without feeling some doubt in a case such as this. Nevertheless, I conclude that the summary judgment record is such that the existence of proximate causation cannot be ruled out as a matter of law.<sup>8</sup>

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<sup>8</sup> There are a number of published cases that address the proximate cause question in the context of food poisoning allegations, many decided before the advent of modern day summary judgment practice. Some of the older cases from the early Twentieth Century involve "ptomaine," a term once used for food poisoning. Judgment as a matter of law has been entered in many cases on the grounds that the evidence was speculative or conjectural in nature and Wendy's has cited a few examples. However, there are also reported cases going the other way, despite reservations expressed by the jurists overseeing them. Significant in many such cases is the fact that the food in question appeared or tasted unwholesome and the willingness of a medical expert to offer the requisite "more likely than not" opinion. Compare Barringer v. Ocean S.S. Co., 134 N.E. 265 (Mass. 1922) (affirming plaintiff's verdict where plaintiff testified to the unwholesome taste of cold meat furnished by the defendant and where the non-

### CONCLUSION

For the reasons set forth above, I **DENY** the motion to bar Dr. Pickus's expert testimony (Docket No. 35), **DENY** the motion to strike (Docket No. 46) and **RECOMMEND** that the Court **DENY** the companion motion for summary judgment (Docket No. 34).

### CERTIFICATE

Any objections to this Order on the motion to bar Dr. Pickus's expert testimony and the motion to strike shall be filed in accordance with Fed. R. Civ. P. 72.

### NOTICE

A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which *de novo* review by the district court is sought, together with a supporting memorandum, and request for oral argument before the district judge, if any is sought, within ten (10) days of being served with a copy thereof. A responsive memorandum and any request for oral argument before the district judge shall be filed within ten (10) days after the filing of the objection.

Failure to file a timely objection shall constitute a waiver of the right to *de novo* review by the district court and to appeal the district court's order.

/s/ Margaret J. Kravchuk  
U.S. Magistrate Judge

March 20, 2006

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treating doctor opined that the plaintiff's symptoms and the timing of their onset were consistent with ptomaine, or "classic" food poisoning: "The evidence, as we have said, was very meagre; but the credibility of the witnesses was for the trial judge, and if he believed them he could find that the plaintiff's case was proved.") and Smith v. Gerrish, 152 N.E. 318 (Mass. 1926) ("The evidence to support the contention of the plaintiff that the mackerel was not wholesome was sufficient to warrant the submission of that issue to the jury.") with Gracey v. Waldorf Sys., Inc., 146 N.E. 232 (Mass. 1925) (distinguishing Barringer on the ground that the record lacked expert testimony "that the plaintiff's illness was caused by the food furnished by the defendant, or that the food was unwholesome"). The apparent unwholesomeness of the food ingested in this case distinguishes some of the cases cited by Wendy's in its discussion of proximate cause, see Hairston v. Burger King Corp., 764 So.2d 176 (La. App. 2000) (affirming trial court finding, following a bench trial, that plaintiff failed to prove Burger King sandwich caused her gastroenteritis, noting plaintiff's testimony that sandwich did not smell or taste unusual); Fuggins v. Burger King, 760 So.2d 605 (La. App. 2000) (lacking evidence of unwholesome appearance, smell or taste). This factor, coupled with the other evidence discussed above, push the instant case over the summary judgment hurdle, in my view.